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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,843	11/18/1999	PAUL JARRETT		1574

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/242,843

Applicant(s)

JARRETT ET AL.

Examiner

Sean R McGarry

Art Unit

1635

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,38,40 and 42-70 is/are pending in the application.
- 4a) Of the above claim(s) 51-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 37,38,40,42-50 and 59-70 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

Art Unit: 1635

DETAILED ACTION

1. Claims 37, 38, 40, 42-50 and 59-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection and is maintained for those reasons set forth in the official action mailed 3/29/01 and 11/20/01.

The instant invention is broadly drawn to an pesticidal composition that comprises a proteinaceous material obtainable from *Xenorhabdus nematophilus* and is encoded by SEQ ID NO:1 or variants thereof. SEQ ID NO: 1 is a nucleic acid sequence of almost 40kb. The specification, for example, indicates that this sequence may contain more than one protein coding sequence that may be insecticidal either alone or when presented together (see page 3, lines 10-15). The specification does not provide one in the art what the coding sequence may be within this large piece of DNA or what the **sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal** activity. The specification has therefor not provided a functional characteristic coupled with a known or disclosed correlation between function and structure. The disclosure of a large nucleic acid sequence does not provide the structure of a pesticidal proteinaceous material that may be composed of various components and or may be processed

Art Unit: 1635

(see page 3, lines 10-15, for example). The specification does not indicate from what reading frame the protein or proteins may be expressed from SEQ ID NO: 1. The specification only provides rudimentary qualities to **supernatants and extracts** (supernatants and extracts are not of equivalent scope to a "composition that may comprise a proteinaceous material obtainable from *Xenorhabdus nematophilus*") such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa.

Claim 59 recites the limitation of 90% identity in reference to a proteinaceous material obtainable from *Xenorhabdus nematophilus* and expressed SEQ ID NO: 1. It is noted that the structure of the proteinaceous material from SEQ ID NO: 1 has not been shown. The limitation of 90% identity draws the invention even further from a written description since that which one would use as the basis of comparison has not been described, for example. One in the art would not know what the structure of such a composition would be based on the general disclosure provided.

Since the instant specification provides only a nucleic acid sequence and does not provide any sequences for the proteinaceous material (a proteinaceous material implies that the scope includes components that may not protein per se, for example. A nucleic acid does not describe other components that may be included in a proteinaceous material, for example) of the claims it is the position of the examiner that an adequate written description of the instant invention is lacking.

Art Unit: 1635

It appears that the specification provides a starting point for one in the art to make a determination of a structure function relationship i.e a plan or first step for obtaining a desired result

2. Applicant's arguments filed 2/19/02 have been fully considered but they are not persuasive and are repeated below.

First it is noted that applicants summary of the telephone communication of 1/23/03 is not agreed with. The assertion that the examiner indicated the specification provided support for enablement and written description was directed to SEQ ID NO:1 per se (ie a nucleic acid that is SEQ ID NO: 1) and not to a proteinaceous material encoded therefrom. The examiner pointed to Example 14 as a courtesy to provide applicant with guidance for what scope of claim drawn to a nucleic acid would be considered adequately described.

Applicant argues that SEQ ID NO: 1 provides a structure for written description. A nucleic acid is not claimed. It is not clear how a correlation between a nucleic acid structure correlates with an uncharacterized "proteinaceous material's" structure, in view of the rejection above, for example.

No protein sequence has been provided in the claims and the claim are specifically drawn to a protein obtainable from a nucleic acid sequence. Applicant argues that they have provided a reference sequence SEQ ID NO: 1 which applicant asserts provides toxicity to insects. This is not disputed. Applicant has shown that cellular extracts from organisms expressing SEQ ID NO: 1

Art Unit: 1635

have toxicity to insects. The specification does not provide a structure function relationship such that one in the art would recognize that applicant was in possession of a proteinaceous material obtainable from *Xenorhabdus nematophilus* that is pesticidal. The only composition disclosed is a cellular extract that possesses such a composition. The claims are not limited to such a composition. The instant specification simply does not provide a description of such a "material". One in the art would not be able to make a composition other than a cellular extract *Xenorhabdus nematophilus* based on the instant specification.

Applicant argues that the specification provides a method that may allow one in the art to determine the protein or proteins responsible for the observed activity. It is noted that an adequate written description of an invention requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; it requires a description of the compound itself (See *Fiers* 984 F.2d at 1170). It is clear that a method of potential isolation of a compound is not a substitute for a description of the claimed protein.

Applicant argues that their subsequent work provides evidence that the specification provides a written description of the invention. It is noted that the publication appears to indicate that the specification, as filed, clearly did not provide a description of the claimed invention since it appears that much experimentation was performed to determine what protein of many potential proteins and further combinations thereof provided for insecticidal activity. It is noted that applicant subsequent work states at page 2067 "[t]he high level of expression of the xptA1 (which, for example, has not been disclosed in the instant specification) gene from the

Art Unit: 1635

bacteriophage P_L promoter may be responsible for our ability to detect insecticidal activity for this single toxin". This statement is made in the context that it is typically for the insecticidal activity to be dependent from more than one protein. The instant specification does not disclose the combination of any protein for toxicity and clearly does not disclose using the bacteriophage P_L promoter to detect activity of the xptA1 protein. Furthermore it is not clear from applicant subsequent work that the toxic proteins function via the oral route. In regard to applicant citation of issue patents in support of written description it is noted that patent applications are each determined on their own merits.

Applicant argues that T7 and T3 promoters are equivalent to the bacteriophage P_L promoter. Applicant provides no evidence that this is true. The context of applicant subsequent work appears to indicate that the use of the bacteriophage P_L promoter allowed them to make the observations they did.

3. Claims 37, 38, 40, 42-50, and 59-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of culture medium and cells per se of the *Xenorhabdus* exemplified as insecticidal compositions, does not reasonably provide enablement for the scope instantly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Art Unit: 1635

The instant invention is broadly drawn to a pesticidal agent which is an extracellular protein from an *Xenorhabdus* species which is encoded by SEQ ID NO: 1 or is a variant thereof and methods of killing or controlling insect pests via such agents.

The instant specification describes the use of cells and supernatant to kill insects. The instant specification does not disclose the killing of any insect via the ingestion of a proteinaceous compound per se but only shows inhibition of growth and death via cells per se and from supernatant. The instant specification does not provide one in the art with guidance for what specific agent is responsible for the death of insects but teaches only that within a 40kb DNA something or things is encoded that causes death of insects. The instant specification does not show any “adaption” of a compound for oral delivery but only shows the “oral delivery” of cells per se and supernatant from cells. One in the art would not know how to adapt a proteinaceous compound based on the disclosure of the instant application other than delivering cells per se or supernatant from cells. The specification, for example, indicates that this sequence may contain more than one protein coding sequence that may be insecticidal either alone or when presented together (see page 3, lines 10-15). The specification does not provide one in the art what the coding sequence may be within this large piece of DNA or what the sequence or structure of the protein or proteins is/are or whether there are in fact two or more proteins that may or may not be needed to provide for an insecticidal activity. The specification only provide rudimentary qualities to supernatants and extracts such as stability and the retention and loss of activity in filters as different as 40kDa and 100 kDa. It is unclear from the disclosure what

Art Unit: 1635

specific compound or combination of compounds is responsible for the insecticidal activity observed from the application of supernatant or cells per se. The instant specification does not point with any particularity to any specific compounds such as those that are claimed. One in the art would be required to make that determination in the practice of the instant invention. Claim 37 is not limited even to the 40kb sequence but reads on any proteinaceous insecticidal protein that may be obtained from any species within *Xenorhabdus* that is encoded by a nucleic acid that may hybridize to SEQ ID NO: 1 under hybridization conditions that have not been specifically defined. One in the art would not know what the structure of such a composition would be based on the general disclosure provided. One in the art would be required to perform undue trial and error experimentation to practice the instant invention. The quantity of experimentation would include, for example, the determination of methods to "adapt proteinaceous compounds" for oral administration, determine what protein or proteins provide for pesticidal properties (for example is it one protein or a combination of two or more, does the protein itself provide toxicity or does the protein convert some substrate into a toxic substance and is this substrate from the cells per se or from the medium provided for growth?). The specification teaches one in the art how to use a cell per se and how to use a supernatant in the killing of insect pests. The instant specification does not teach one how to make or use any specific pesticidal proteins as is instantly claimed.

4. Applicant's arguments filed 2/19/03 have been fully considered but they are not persuasive.

Art Unit: 1635

Applicant argues that Examples 7-9 demonstrate the same unexpected oral activity of SEQ ID NO: 1. It is noted that examples 7-9 do not allow or provide one in the art with any guidance on how to make a composition other than a cellular extract that may contain a pesticidal material. Applicant also argues that there is no justification for refusing claims based on a sequence simply because they may exclude other from using such subsequences. It is apparent from the rejections of record that this is clearly not the basis for any rejection of record.

5. Those rejections set forth in the Official Action mailed 11/20/02 and not repeated herein are withdrawn.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean McGarry whose telephone number is (703) 305-7028. The examiner can be reached M-Th 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. Papers should be faxed to Art Unit 1635 via the PTO Technology Center Fax

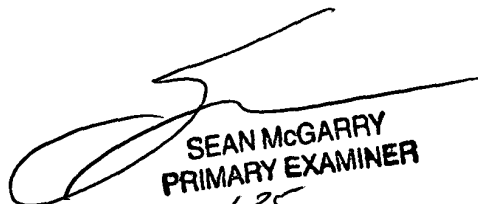
Art Unit: 1635

Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1635 FAX number is (703) 308-4242 or (703) 305-3014. NOTE: If Applicant **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sean McGarry

May 1, 2003



SEAN MCGARRY
PRIMARY EXAMINER
1635